

Application No.: 10/596,103  
Amendment and Response dated November 10, 2010  
Reply to Office Action of September 17, 2010  
Docket No.: 1848-7 PCT/US/RCE  
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### REMARKS

Applicant respectfully requests entry and consideration of the Amendment submitted herewith.

### STATUS OF CLAIMS

Claims 17-64 are pending. Please amend Claims 24 to correct a grammatical error therein.

Support for the claim amendment can be found throughout the specification and in the claims as originally filed. No new matter has been added.

### 35 U.S.C. §102 REJECTIONS

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by either Petzelbauer (US 2004/0192596) and Petzelbauer (US 2007/0037749). Additionally, Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by WO 02/48180 published on June 20, 2002 in German (Petzelbauer).

Applicants wish to clarify the record. The Office Action at page 9 misquotes Applicants statement as reflected in the bolded text which should read “methods for treating” instead of “method of shock”

Applicants argue that methods of treating inflammation are distinct from methods of treating shock... the disclosure of **method of shock** (sic) or preventing inflammation in reference WO 02/48180 was found to not be of particular relevance to the determination of novelty and inventive step of methods for treating shock in the presently claimed invention.

The presently claimed invention is directed to methods for treating shock. As detailed in the Background of the Invention section of the instant application, “[s]hock is an acute complication of **many different pathological conditions** characterized by the inability of the cardiovascular system to maintain an adequate perfusion pressure” (Emphasis added, see, paragraph 2, first sentence). Specifically, the term “shock” is defined by MedTerms medical dictionary as follows:

In medicine, shock is a critical condition brought on by a sudden drop in blood flow through the body. There is failure of the circulatory system to maintain adequate blood flow. This sharply curtails the delivery of oxygen and nutrients to vital organs. It also compromises the kidney and so curtails the removal of wastes from the body. Shock can be due to a number of different mechanisms including not enough blood volume (hypovolemic shock) and not enough output of blood by the heart (cardiogenic shock). The signs and symptoms of shock include low blood pressure (hypotension), overbreathing (hyperventilation), a weak rapid pulse, cold clammy grayish-bluish (cyanotic) skin, decreased urine flow (oliguria), and mental changes (a sense of great anxiety and foreboding, confusion and, sometimes, combativeness).

Shock is a major medical emergency. It is common after serious injury. Emergency care for shock involves keeping the patient warm and giving fluids by mouth or, preferably, intravenously.

As reflected in both the excerpt from the instant application as well as the definition of shock above, shock is a condition characterized by a reduction in blood flow that can be caused by different mechanisms.

As noted by the Examiner, published patent application US 2004/0192596 discloses the same general formula II as well as a peptide sequence (see SEQ ID NO: 294) corresponding to SEQ ID NO: 8 of the instant application as well as methods of preventing inflammation (see Claims 14 and 21) or treating rejection of a transplanted tissue in a subject comprising administering thereto an effective amount of a peptide having the general formula II.

As noted by the Examiner, published patent application US 2007/0037749 discloses a peptide sequence (see SEQ ID NO: 294) corresponding to SEQ ID NO: 3 of the instant application, "preparation of pharmaceutical compositions for the therapy or prevention of local and/or generalized inflammations in the body...prevention and/or therapy of the rejection occurring after organ transplants..." (see paragraph [0034]).

As noted by the Examiner, published patent application WO 02/48180 discloses a peptide having general formula II as well as a peptide sequence (see SEQ ID NO: 11) corresponding to SEQ ID NO: 3 of the instant application and methods of treating inflammation in a subject comprising administering thereto an effective amount of a peptide having the general formula II.

The term "inflammation" is defined by MedTerms medical dictionary as follows:

A basic way in which the body reacts to infection, irritation or other injury, the key feature being redness, warmth, swelling and pain. Inflammation is now recognized as a type of nonspecific immune response.

Contrary to the Examiner's position, the etiology of inflammation and shock is not necessarily the same. Further, the manifestation of inflammation and shock differ. Accordingly, the patient population treated for shock or inflammation is not necessarily the same patient population. Likewise, the patient population treated for shock or inhibition of inflammation differ.

Although US 2004/0192596, US 2007/0037749, WO 02/48180 and the instant application include the step of administering a peptide having the sequence of SEQ ID NO: 8 of the instant application, the therapeutic indication for which the peptide is administered differs between the cited art and the instant application. Likewise, the patient population receiving the peptide for such indication is not necessarily the same patient population. Nowhere do any of US 2004/0192596, US 2007/0037749, WO 02/48180 disclose or suggest methods for treating shock using such peptides. Further, a skilled artisan would not have a reasonable expectation of success in treating shock based on the disclosure of US 2004/0192596, US 2007/0037749 or WO 02/48180. Thus, the cited art cannot anticipate nor render obvious the claimed invention.

In light of the aforementioned remarks, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. §102(b) and §102(e) of Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62.

**DOUBLE PATENTING REJECTIONS**

**Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62** stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the following:

- Claims 1-4 of U.S. Patent No. **7,271,144**
- Claims 1-4 of copending Application No. **11/899,611**, now U.S. Patent No. **7,811,985**
- Claims 1-3 of U.S. Patent No. **7,494,973**
- Claims 6-7 of copending Application No. **12/121,533**
- Claims 6-7 of copending Application No. **12/121,544**
- Claims 1-2 and 4-5 of copending Application No. **12/158,670**

As discussed in the 35 U.S.C. §102 rejections above, methods of treating shock disclosed in the instant application are neither anticipated nor rendered obvious by methods of treating inflammation disclosed in US 2004/0192596 and US 2007/0037749. Notably, U.S. patent 7,271,144 (U.S.S.N. 10/459,030) corresponds to published patent application US 2004/0192596, U.S. patent 7,494,973 (U.S.S.N. 11/542,050) corresponds to published patent application US 2007/0037749) and U.S. application 11/899,611 (U.S. Patent No. 7,811,985) is a divisional application of U.S.S.N. 10/459,030 (published patent application US 2004/0192596). Likewise, Applicants argue that methods of treating shock disclosed in the instant application are not rendered obvious by methods of treating inflammation disclosed in U.S. patent 7,271,144, U.S. patent 7,494,973 and U.S. application 11/899,611 (U.S. Patent No. 7,811,985). Consequently, Applicants respectfully request withdrawal of the double patenting rejections of Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 in view of U.S. patent 7,271,144, U.S. patent 7,494,973 and U.S. application 11/899,611 (U.S. Patent No. 7,811,985).

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The instant application filed on June 24, 2005 claims priority to Austrian Application A1087/2004 filed on June 25, 2004 and Austrian Application A40/2005 filed on January 13, 2005. Thus, the subject application precedes U.S. Application Nos. 12/121,533, filed May 15, 2008, 12/121,544, filed May 15, 2008 and 12/158,670, filed September 5, 2008 which claims priority to Austrian Application A 2067/2005, filed December 23, 2005. Upon issuance, the instant application would presumably expire prior to the expiration of any patent issuing based on U.S. Application Nos. 12/121,533, 12/121,544 or 12/158,670. Nonetheless, upon indication of allowable subject matter, Applicants will consider the need to file one or more terminal disclaimers to overcome these obviousness-type double patenting rejections.

Additionally, Applicants point out that the invention of the instant application as well as subsequently filed U.S. Application Nos. 12/121,533, 12/121,544 or 12/158,670 were commonly owned at the time of the later inventions.

### **35 U.S.C. §103 REJECTIONS**

**Claims 17-32, 35-38, 41-44, 47-50, 53-56 and 59-62** stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over **Petzelbauer** (WO 02/48180 published on June 20, 2002 in German) in view of **Bevec et al.** (US 2004/0122058).

**Claims 17-28, 30-33, 36-39, 42-45, 48-51, 54-57 and 60-63** stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over **Petzelbauer** (WO 02/48180) in view of **Thurkauf et al.** (WO 02/49993).

**Claims 17-28, 30-34, 36-40, 42-46, 48-52, 54-58 and 60-64** stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over **Petzelbauer** (WO 02/48180) in view of **Yat et al.** (WO 94/07815).

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As discussed in the 35 U.S.C. §102 rejections above, methods for treating shock differ from methods for preventing or treating inflammation. Nowhere does WO 02/48180 disclose or suggest methods for treating shock. Further, a skilled artisan would not have a reasonable expectation of success in treating shock based on the disclosure of WO 02/48180 as, independent of cause, the manifestation of shock is different from inflammation and the patient population treated for each therapeutic indication is not necessarily the same.

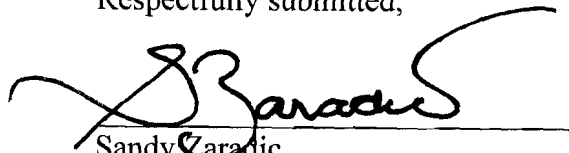
Neither Bevac *et al.*, Thurkauf *et al.* nor Yat *et al.* cure the deficiency of WO 02/48180. Accordingly, the claimed invention cannot be rendered obvious by WO 02/48180, either alone, or in combination with any of Bevac *et al.*, Thurkauf *et al.* nor Yat *et al.*

In view of the aforementioned remarks, Applicants respectfully request withdrawal of these rejections under 35 U.S.C. §103.

### **CONCLUSION**

Applicants believe Claims 17-64 are in condition for allowance and respectfully request the same. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Sandy Zaradic', is written over a horizontal line.

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